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Re-evaluation Note REV2016-15

Special Review of Dichlobenil: Proposed Decision for Consultation

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1.0 Introduction

Pursuant to subsection 17(2) of the *Pest Control Products Act*, the Pest Management Regulatory Agency (PMRA) has initiated a special review of pest control products containing dichlobenil based on the European Decision (European Commission, 2011a) and the Norwegian Decision (Rotterdam Convention, 2000) to prohibit the use of such products in Europe and Norway due to environmental concerns. The initiation of the special review was announced in December 2013 (Canada, 2013).

As required by subsection 18(4) of the *Pest Control Products Act*, the PMRA has evaluated the aspects of concern related to the pest control products containing dichlobenil that prompted the special review. The aspects of concern are relevant to the environment and were identified as:

- the potential for a metabolite of dichlobenil, 2,6-dichlorobenzamide (BAM), to leach into groundwater;
- potential for long-range transport of the metabolite BAM;
- potential acute risk of dichlobenil to birds;
- potential chronic risk of dichlobenil and the metabolite BAM to birds and mammals; and
- potential risk of dichlobenil to the aquatic environment.

2.0 Uses of Dichlobenil in Canada

Dichlobenil is a benzonitrile herbicide currently registered for commercial and domestic use in Canada as a granular formulation for the control of annual grasses, broadleaf weeds and certain perennial weeds on food and non-food use-sites. Dichlobenil is also registered for commercial and domestic use as a wettable powder formulation for the control of root growth in sewer and storm systems. All currently registered pest control products containing dichlobenil (see Appendix I) are considered in this special review.

The PMRA published the re-evaluation decision for dichlobenil in 2006 (Canada, 2006). As a result of the re-evaluation, the PMRA determined that products containing dichlobenil do not present unacceptable risks to human health and the environment when used according to the revised conditions of use. The revised use conditions have been implemented and include mitigation measures to further protect workers, homeowners and the environment.

3.0 Aspects of Concern that Prompted the Special Review

Based on the review of the European decision (European Commission, 2011a) and the Norwegian decision (Rotterdam Convention, 2000a), the PMRA has identified the aspects of concern that prompted the special review of pest control products containing dichlobenil as:

- the potential for leaching of the metabolite BAM (2,6-dichlorobenzamide) into groundwater
- potential for long-range transport of the metabolite BAM
- potential acute risk of dichlobenil to birds

- potential chronic risk of dichlobenil and the metabolite BAM to birds and mammals
- potential risk of dichlobenil to the aquatic environment

The European Commission indicated that there was insufficient information to address the nature of residues of the metabolite BAM in processed commodities (European Commission, 2011a). Also, Norway indicated that there is insufficient information to properly evaluate possible health effects of dichlobenil (Rotterdam Convention, 2000a). Taking into consideration that no specific concerns related to possible health effects were identified by the European Commission or Norway, the aspects of concern for this special review were limited to those described above.

4.0 PMRA Evaluation of the Aspects of Concern that Prompted the Special Review

Following the initiation of the special review of dichlobenil, the PMRA requested information from provinces and other relevant federal departments and agencies, in accordance with subsection 18(2) of the *Pest Control Products Act*. In response, water monitoring data for dichlobenil and BAM were received.

In order to evaluate the aspects of concern for dichlobenil, the PMRA has considered currently available relevant scientific information, which includes information considered for the re-evaluation of dichlobenil (Canada, 2005) and any relevant information obtained since then (for example, available groundwater and surface water monitoring data for dichlobenil and BAM, information from the European Union, as well as relevant information published by the United States Environmental Protection Agency [USEPA]) (United States, 2007 and 2012).

No information related to the aspects of concern was identified in the Canadian incident report databases.

4.1 Potential for Leaching of the Metabolite BAM into Groundwater

BAM is a major soil metabolite of dichlobenil. In lab studies, BAM accounted for up to 13 % of the applied radioactivity in aerobic soil (United States, 2012). BAM was detected in field studies at up to 4.9 % of the maximum dichlobenil concentration in soil. BAM is stable to hydrolysis, to aqueous photolysis, and to biodegradation in soil and water (United States, 2007). BAM is more mobile than dichlobenil and has the potential to leach to groundwater (K_{oc} = 34 to 54 ml/g). In terrestrial field studies, BAM leached to the deepest sampling depth (up to 84-96 inches deep) (United States, 2012).

PMRA considered modelling and monitoring data for assessing levels of BAM in groundwater.

Levels of BAM in groundwater were estimated using modelling based on the dichlobenil application rate of 11 kg a.i./ha and conservative environmental fate assumptions for BAM. The acute and chronic estimated ground water concentration for BAM from use of dichlobenil was 56.2 µg/L (United States, 2007 and 2008).

Levels of BAM associated with dichlobenil use in a small scale American groundwater monitoring study were also considered by the PMRA. Sampling included 26 wells monitored for a period of one year in areas situated around fields with at least five years of historical use of dichlobenil in the states of Massachusetts, Wisconsin, Oregon, and Washington. The maximum BAM concentration detected was 13.8 µg/L.

In addition, Canadian monitoring data for BAM in groundwater indicated BAM detections in 16 out of 103 domestic wells. The maximum BAM concentration detected was 2.5 µg/L.

In addition to assessing the potential for the metabolite BAM to leach into groundwater from use of pest control products containing dichlobenil, the PMRA has conducted a scientifically based drinking water risk assessment to determine whether exposure to BAM through Canadian groundwater presents a potential unacceptable risk to Canadians. The estimated levels of BAM in groundwater under current conditions of use were incorporated into dietary risk assessments to assess the potential risk (acute and chronic) from exposure through drinking water.

Dietary Risk Assessment

For assessing risks from potential residues in food (including drinking water), the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. Due to database deficiencies, and the systemic neurotoxic potential of BAM, the 10-fold *Pest Control Products Act* factor (PCPA factor) was retained for both acute and chronic dietary (food + drinking water) BAM risk assessments.

The chronic dietary assessment is based on an acceptable daily intake (ADI) for BAM of 0.0045 mg/kg bw/day, which was derived using a no observed adverse effect level (NOAEL) of 4.5 mg/kg bw/day from a chronic oral toxicity study in dogs and an uncertainty factor of 1000 (includes 10-fold PCPA factor). The assessment assumes a drinking water concentration for BAM from dichlobenil use of 56.2 µg/L based on groundwater modelling (highest estimated value from modelling and monitoring). The chronic aggregate exposure to BAM from food and drinking water from dichlobenil sources is considered acceptable and below the level of concern, ranging from 25.8 % to 93.1 % of the ADI for all population subgroups. The highest exposed population subgroup was infants (<1 year old).

The acute dietary assessment is based on an acute reference dose (ARfD) for BAM of 0.1 mg/kg bw for the general population based on a lowest observed adverse effect level (LOAEL) of 100 mg/kg bw, and an uncertainty factor of 1000 (includes 10-fold PCPA factor). The ARfD for BAM for females aged 13-49 years was determined to be 0.03 mg/kg bw based on a NOAEL of 30 mg/kg bw, and an uncertainty factor of 1000 (includes 10-fold PCPA factor). The acute dietary exposure assessment assumes a drinking water concentration for BAM from dichlobenil use of 56.2 µg/L based on groundwater modelling (highest estimated value from modelling and monitoring). The acute aggregate exposure to BAM from food and drinking water from dichlobenil sources was 4.69 % of the ARfD for the general population, and 11.12 % for females aged 13-49, which is considered acceptable, and below the level of concern.

The levels of BAM detected in the available Canadian and American groundwater monitoring data are less than a quarter of the modelled levels used in the dietary risk assessment (maximum concentrations of 2.5 µg/L and 13.8 µg/L, respectively) and are not expected to be of concern.

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal and inhalation). Residential and non-occupational exposure to the metabolite BAM is expected to be minimal. Therefore aggregate exposure is limited to exposure from food and drinking water only, which poses no potential risks of concern, as discussed above.

No common mechanism of toxicity has been identified for the metabolite BAM and other active ingredients or metabolites. Therefore, a cumulative risk assessment is not required for BAM.

In summary, based on the dietary risk assessment for BAM, which includes drinking water, the PMRA concludes that there are no potential acute or chronic risks of concern from groundwater-sourced drinking water under the current conditions of use of dichlobenil. No additional risk mitigation measures are required.

The precautionary label statements for leaching are proposed to be updated to the current labelling standard (Appendix I).

4.2 Potential for Long-range Transport of the Metabolite BAM

The chief concern for persistence in air is to avoid the movement of contaminants to remote regions where they bioaccumulate through the aquatic and terrestrial food web. In Canada, this concern is assessed by evaluating substances against the Toxic Substances Management Policy (TSMP) (Canada, 1995). The PMRA's implementation of the TSMP is outlined in DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*.

The atmospheric half-life of dichlobenil is estimated to be 63 days (USEPA, 2012). However, laboratory studies indicate that its presence in the atmosphere will be limited to 1.4 days by reaction of vapour phase dichlobenil with photochemically-produced hydroxyl radicals (direct photolysis) (European Commission, 2010). The laboratory half-life does not exceeds the regulatory criteria for persistence in air of 2 days indicating that dichlobenil is not likely to undergo long range atmospheric transport. Dichlobenil is not expected to bioaccumulate as its log K_{ow} of 2.7 is less than the criteria of 5.0 as per the Toxic Substances Management Policy (TSMP). In addition, the bioconcentration factor in whole fish is 63 (USEPA, 2012), which is much lower than the TSMP level of concern of >5000 and indicates that bioaccumulation through the aquatic and terrestrial food web will not occur.

When formed in the environment, the metabolite BAM, has potential to undergo long range atmospheric transport based on the modelled atmospheric half-life of 3.7 days (European Commission, 2010). This half-life exceeds the regulatory criteria for persistence in air of 2 days. Since BAM will exists in both vapour and particulate phases in the atmosphere, deposition of

particulate phase BAM will occur by wet and dry processes. Therefore, BAM may undergo long range atmospheric transport, particularly in the vapour phase. Despite this, since the log P_{ow} is 0.38-0.51 (European Commission, 2010), bioaccumulation through the aquatic and terrestrial food web will not occur. Further, the bioconcentration factor for BAM in fish is 10 (HSDB, 2001) which is lower than the TSMP level of concern of >5000 and indicates that bioaccumulation through the aquatic and terrestrial food web will not occur.

On this basis, the potential for long-range transport of dichlobenil and the metabolite BAM is not of concern. No further mitigation is required.

4.3 Potential Acute Risk of Dichlobenil to Birds

Birds may be exposed to granular dichlobenil by ingesting granules when foraging for food or consuming intentionally for grit. Dichlobenil granules are composed of an inorganic carrier which has no nutritional value. Thus, birds are not expected to consume dichlobenil granules intentionally as food. Exposure through other routes, including contact with skin/feathers or drinking water contaminated by granules, is expected to be minimal. The ingestion of granules is considered to be the main route of exposure for birds and is the focus of the risk assessment.

Dichlobenil is practically non-toxic to slightly toxic to birds on an acute basis. The most sensitive acute endpoint, the oral LD_{50} of 683 mg/kg bw/day for the bobwhite quail (Canada, 2005), was used to estimate the acute risk of dichlobenil to birds, adjusted by an uncertainty factor of 10 to account for potential differences in species sensitivity as well as varying protection levels (for example, community, population, individual).

For the application rate of 11 kg a.i./ha, the number of dichlobenil granules required to reach the adjusted LD_{50} was determined for three body size classes of birds. Birds of 20 g, 100 g and 1 kg would have to consume 48, 240 and 2405 granules, respectively, in one day to reach the adjusted LD_{50}. The probability that birds would find sufficient granules on the soil surface when searching for soil particles (grit) to reach the toxicity endpoint was determined to be close to zero for all three size classes.

Canadian labels currently specify to apply dichlobenil granules to moist soil, or to thoroughly water-in, soil-incorporate or cover granules with moist mulch if the soil is dry. These practices would release dichlobenil from the granule carrier following contact with moisture, which would minimize the amount of time that the active ingredient will be present on the granules, and minimize potential exposure of dichlobenil to birds.

Therefore, the PMRA concludes that the uptake of dichlobenil-treated granules is not expected to pose an acute risk of concern to birds when granules are applied according to current label instructions.

4.4 Potential Chronic Risk of Dichlobenil and the Metabolite BAM to Birds and Mammals

The potential chronic risk of dichlobenil from the consumption of grit was assessed based on a no observed effect level (NOEL) of 14.1 mg a.i./kg bw/day for the bobwhite quail (European Union, 2010). Birds of 20 g, 100 g and 1 kg would have to consume 10, 50 and 496 granules in one day, respectively, to reach the NOEL. The probability that birds would find sufficient granules on the soil surface when searching for soil particles (grit) to reach the chronic toxicity endpoint was determined to be close to zero for all three size classes. Furthermore, as discussed above, when dichlobenil granules are applied according to current Canadian label instructions, the active ingredient is expected to be released from the granules following application. Thus, the PMRA concludes that long-term exposure of birds to dichlobenil from the consumption of granules is limited, and chronic risk is not of concern. Chronic exposure of the metabolite BAM to birds from consumption of dichlobenil-treated granules as grit is not expected based on the dichlobenil use pattern, therefore, the risk is also not of concern.

The consumption of earthworms contaminated with dichlobenil or the metabolite BAM was considered as a likely alternative route of potential chronic exposure for birds. Avian toxicity data were not available for BAM therefore it was assumed that BAM was 10 times more toxic to birds than dichlobenil. Based on a screening level risk assessment for birds, exposure to either dichlobenil or BAM was below the level of concern for all sizes of birds.

Mammals do not actively search out inorganic particles for consumption as grit and consumption of granules would only occur inadvertently. Therefore, it is assumed that the actual number of granules that would be consumed would be very low and the chronic risk of dichlobenil to mammals would be negligible.

The chronic risk assessment for mammals from the consumption of contaminated earthworms was based on a NOAEL of 3 mg a.i./kg bw/day for dichlobenil (European Union, 2010; United States, 2012) and a NOAEL of 13.5 mg a.i./kg bw/day for BAM (European Union, 2010). Based on the screening level risk assessment for mammals, exposure to either dichlobenil or BAM was below the level of concern.

The PMRA concludes that under the current conditions of use of dichlobenil, there are no chronic risks from dichlobenil and the metabolite BAM to birds and mammals that are of concern. No additional risk mitigation measures are required.

4.5 Potential Risk of Dichlobenil to the Aquatic Environment

The risk of dichlobenil to the aquatic environment was assessed for the two major Canadian use scenarios: 1) application of the granular products to soil for control of weeds; 2) sewer uses of the wettable powder for control of root growth in pipes.

Dichlobenil is volatile and stable to hydrolysis. Dichlobenil photolyzes in shallow, clear surface waters (half-life of 10 days). In laboratory studies, dichlobenil is stable to aquatic biodegradation in aerobic and anaerobic systems; however, dichlobenil dissipates in aerobic aquatic systems due to volatilization (half-life of 2.4 days). In aquatic field dissipation studies (ponds), dichlobenil is slightly to moderately persistent in surface waters (DT_{50}s of 15-69 days) (USEPA, 2012).
The most sensitive endpoint for dichlobenil is an EC_{50} of 0.030 ppm a.i. for the aquatic vascular plant *Lemna gibba* (duckweed). Fish early life stage toxicity studies indicate that dichlobenil may chronically affect fish at levels of 0.33 ppm. Aquatic invertebrate life-cycle studies indicate that dichlobenil may chronically affect aquatic invertebrates at concentrations of 0.75 ppm (Canada, 2005).

Granular Use on Soil: Dichlobenil applied to soil has the potential to contaminate surface water from runoff (based on the low soil/water partitioning coefficient for dichlobenil). Since dichlobenil is applied as a granular formulation by spreader equipment only, drift is not expected.

Aquatic water modelling was performed, to calculate expected environmental concentrations (EEC) based on runoff from a 10 hectare field to a 1 hectare water body, 2 meters deep, based on application rates ranging from 2.2 kg a.i./ha to 22 kg a.i./ha (Canada, 2005, United States, 1998). Using maximum EECs and the most sensitive aquatic species endpoint (*Lemna gibba*), potential risk to non-target aquatic vascular plants from runoff was identified. There were no risks of concern identified for other aquatic organisms. The modelling assumptions concerning losses due to runoff are conservative and the actual amount of dichlobenil in surface water is expected to be lower, being dependent on climate and environmental conditions (United States, 1998).

In addition to modelling, the PMRA considered available surface water monitoring information. Based on the highest concentration of dichlobenil detected in Canadian surface water the level of concern is not exceeded for aquatic vascular plants. Current Canadian labels require granules to be applied to moist soil, watered-in, incorporated into soil or covered with moist mulch, reducing the potential for runoff. Standard label statements to minimize runoff are already included on commercial labels.

Concentrations of dichlobenil in the aquatic environment from the use of granular products are not expected to pose a risk of concern. The label statements for run-off, and management of cranberry effluent water, are proposed to be updated to the current labelling standard (Appendix I).

Sewer Use: A screening level aquatic risk assessment was conducted for the commercial dichlobenil sewer product based on endpoints for fish, aquatic invertebrates and aquatic plants (*Lemna gibba*). Based on information on the label, an expected environmental concentration of 0.97 mg dichlobenil/L (ppm) of undiluted sewage effluent was calculated assuming 5 % loss due to volatilization and adsorption during waste water treatment. Based on the screening level risk assessment, the use of the commercial sewer use product may pose a risk to non-target aquatic organisms in undiluted sewage effluent; the level of concern is exceeded for fish, aquatic invertebrates and plants. The potential risk to aquatic species is identified on the current dichlobenil commercial sewer label.

Several conditions of use already included on the commercial label minimize the potential exposure of aquatic systems to dichlobenil and reduce potential risk. The use of the commercial sewer product is controlled and requires appropriate certification recognized by the provincial/territorial pesticide regulatory agency where the application occurs. Sewer applications are limited to systems where the waste water is treated before release to the environment. Licenced applicators must notify the sewage treatment plant prior to application so that the biological breakdown process in the plant can be monitored during the application. If any adverse effects are noted within the sewage treatment plant, the application must cease. Applications where insufficient dilution is possible (for example, close proximity to the sewage plant or applications conducted at night), are required to use reduced application rates.

Furthermore, once released to the environment, treated sewage will be diluted in the receiving water body. Dilution in receiving water bodies varies by orders of magnitude across Canada and relies on many site specific variables including the flow rate of the sewage effluent as well as the mixing characteristics and the seasonal variation in the flow rate of the receiving water body. A generic dilution factor of 10 was considered representative and protective of water bodies receiving sewage effluents across Canada. When applying this dilution factor, the level of concern is not exceeded for aquatic invertebrates and fish, but is exceeded for aquatic plants. This indicates that non-target aquatic plants may be at risk following the sewer use of dichlobenil in cases of low dilution of treated sewage effluent with the receiving compartment when the product is used at the maximum rate authorized on the label.

Domestic sewer products have similar precautionary label statements indicating the toxicity to non-target organisms and that they should only be used in sewer and storm systems where waste water will be treated or controlled. Domestic sewer products are generally used on a smaller scale than the commercial product and are expected to be used sporadically.

Dichlobenil is not expected to persist in the aquatic environment. When used according to label directions, risks to the aquatic environment from the use of dichlobenil in sewers are not expected to be of concern.

The label statements regarding toxicity to aquatic organisms and general restrictions for aquatic sites are proposed to be updated to the current labelling standard (Appendix I).

5.0 Proposed Special Review Decision for Dichlobenil

Evaluation of available scientific information related to the aspects of concern indicated that the registered products containing dichlobenil do not pose unacceptable risk to human health and the environment taking into account to current conditions of use. On this basis, the PMRA is proposing to confirm the current registration of products containing dichlobenil for sale and use in Canada pursuant to subsection 21(1) of the *Pest Control Product Act*. The PMRA is proposing that certain environmental precautions and directions for use label statements be added or updated to meet the current PMRA labelling standard and standardize statements across labels.

This proposed special review decision is a consultation document.[1] The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

6.0 Next Steps

Before making a special review decision on dichlobenil, the PMRA will consider all comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on dichlobenil. The PMRA will then publish a special review decision document, which will include the decision, the reasons for it, a summary of the comments received on the proposed decision and the PMRA's response to these comments.

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Appendix I Registered Products Containing Dichlobenil as of 10 August 2016

Registration Number	Marketing Class	Product Name	Formulation	Guarantee
12533	Commercial	CASORON G-4 GRANULAR HERBICIDE	Granular	4%
19963	Technical	TECHNICAL DICHLOBENIL	Solid	99%
20217	Manufacturing Concentrate	CASORON 85W MANUFACTURING CONCENTRATE	Wettable powder	85%
20233	Domestic	CASORON GRANULAR HERBICIDE	Granular	2%
25934	Domestic	ROOTX WP HERBICIDE	Wettable powder	0.55%
26435	Domestic	ROOTX FDU WP HERBICIDE	Wettable powder	0.55%
26436	Domestic	RESIDENTIAL ROOTX 15	Wettable powder	0.55%
26437	Domestic	RESIDENTIAL ROOTX 30	Wettable powder	0.55%
30224	Commercial	SANAFOAM A (A COMPONENT OF THE SANAFOAM® VAPOROOTER® II TANK MIX CONCEPT)	Wettable powder	20%

Appendix II Label Amendments for Products Containing Dichlobenil

1. Potential for leaching of the metabolite BAM into groundwater

Registration number 12533: Replace existing leaching statements in the section entitled **ENVIRONMENTAL HAZARDS** with the following statement:

> *"This product demonstrates the properties and characteristics associated with chemicals detected in ground water. The use of [product name] in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination."*

2. Potential Risk of dichlobenil to the aquatic environment

Registration number 12533: Replace existing runoff statements in the section entitled **ENVIRONMENTAL HAZARDS** with the following statements in a section entitled **ENVIRONMENTAL PRECAUTIONS**:

> *"To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.*
>
> *Avoid application when heavy rain is forecast.*
>
> *Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body."*

Registration number 12533: The following statement is to be included in a section entitled **DIRECTIONS FOR USE**:

> *"To minimize surface water contamination when used on cranberries, all effluent water must be impounded and held for one day prior to release."*

All dichlobenil end-use products, if not already included: The following statement is to be included in a section entitled **ENVIRONMENTAL PRECAUTIONS**:

> *"Toxic to aquatic organisms."*

All dichlobenil end-use products, if not already included (as appropriate for commercial (C), domestic (D) products): The following statements are to be included in a section entitled

DIRECTIONS FOR USE:

"As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests." C

"DO NOT apply to any body of water." D

"DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes." C, D

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